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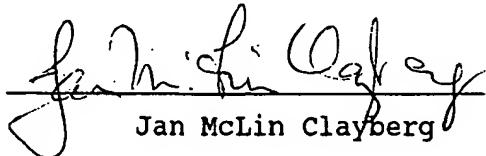
DECLARATION

I, Jan McLin Clayberg, translator, having an office at 5316 Little Falls Road, Arlington, Virginia 22207, USA, declare that I am well acquainted with the English and German languages and that to the best of my knowledge and ability, the appended translation is a true and faithful translation of

International Patent Application PCT/EP 99/04628.

All statements made herein are to my own knowledge true and all statements made on information and belief are believed to be true; and further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any proceeding bearing thereon.

Date May 26, 2000



Jan McLin Clayberg

INTERVERTEBRAL IMPLANT

The invention relates to an intervertebral implant, having an upper part that has a support face for a vertebra and a lower part that has a support face for an adjacent 5 vertebra, on each of which parts engagement elements, which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, in order to minimize the structural height of the intervertebral implant upon insertion into an intervertebral space.

10 One such intervertebral implant is known for instance from U.S. Patent 5,314,477. This intervertebral implant is used to replace a disk removed from the intervertebral space, and accordingly the intervertebral implant must have a relatively low structural height, since it has to fit into 15 the gap between vertebrae. This is particularly difficult if an additional pivot insert is also embedded between the upper part and the lower part, as is the case in the known intervertebral implant of U.S. Patent 5,314,477.

20 But even in two-piece intervertebral implants, difficulties also arise, especially if the implants also have pins and other protrusions on their support faces that are intended for anchoring the intervertebral implant in the bone. Often, these parts can be inserted only by widening 25 the intervertebral space greatly. Not only is this difficult, but it also presents the risk of injuries.

Since the intervertebral space has a relatively low height, it is also difficult for engagement elements that a manipulation instrument can engage to be secured to both parts of the intervertebral implant. It is conventional to

have such manipulation instruments engage the upper part and the lower part separately, for instance by means of pins that are inserted into bores on the upper part and lower part, so that with the manipulation instrument, the two parts of the
5 intervertebral implant can be inserted into the intervertebral space and can optionally also be varied in terms of their spacing from one another, thereby allowing a certain spreading open of the intervertebral space. In this respect, reference is made to the pincerlike manipulation
10 instrument of U.S. Patent 5,314,477.

Because of the strong forces, it is necessary to provide a certain structural height for the engagement elements; for instance, the receiving bores must have a certain diameter. This dictates a minimum structural height
15 for the upper part and for the lower part, and in conventional intervertebral implants, the structural heights of the upper part and lower part are thus added together, so that even if the upper and lower parts rest directly on one another, a relatively great structural height of the
20 intervertebral implant is still unavoidable.

It is the object of the invention to embody an intervertebral implant of this generic type in such a way that the minimum structural height is reduced, to make it easier to insert the intervertebral implant into the
25 intervertebral space.

In an intervertebral implant of the type described at the outset, this object is attained in accordance with the invention in that it is proposed that the upper part and lower part each have protrusions and recesses aimed at the
30 respectively other part, which are offset laterally from one another in such a way that when the upper part has been

brought close to the lower part they mesh with one another; and that the engagement elements on the upper part and on the lower part are each disposed in protrusions of these parts in such a way that the engagement elements of the upper part and 5 lower part are located side by side and at least partly overlap in the direction of the height of the intervertebral implant.

In such an embodiment, a minimal structural height of 10 the two intervertebral implant parts resting on one another can be attained, since the engagement elements, which cannot fall below a minimal structural height, are each disposed in protrusions of the upper part and lower part, or in other words in the parts of the upper part and lower part that have the greatest structural height. These regions of great 15 structural height are embodied as protrusions, next to which are respective recesses, into which the protrusions of the respectively other part can dip. As a result, on the one hand, the engagement elements for the manipulation instruments are located side by side, and on the other, they 20 can at least partly overlap, so that the total structural height of the parts resting on one another of the intervertebral implant can be reduced markedly compared to conventional intervertebral implants. The result is accordingly an internested arrangement of the upper and lower 25 parts, with maximal exploitation of the available material height.

It is favorable if the engagement elements are 30 insertion openings for pinlike retaining elements of a manipulation instrument; because of the described construction, these insertion openings can have a relatively large diameter and can thus receive strong retaining pins, and nevertheless a relatively low structural height of the

intervertebral implant with parts resting directly on one another is obtained.

It is advantageous if the insertion openings extend substantially parallel to the support faces; once again, this 5 prevents an increase in the structural height of the intervertebral implant parts.

In a preferred embodiment, it is provided that the lower part has a central indentation, opposite the lower support face, which indentation is surrounded by a U-shaped 10 edge. Thus with the lower part and upper part resting directly on one another, the indentation serves to receive a protrusion on the upper part.

It is advantageous if the upper part has a central protrusion that fits substantially in complimentary fashion 15 into the indentation; that is, the total volume of the indentation is utilized for the protrusion.

It is also advantageous if the engagement elements of the lower part are disposed on the two ends of the U-shaped edge, or in other words are located on the outside.

20 Conversely, the engagement elements of the upper part can be disposed on the central protrusion of the upper part, or in other words are located farther inward than the engagement elements of the upper part.

25 In particular, the engagement elements of the upper part can be disposed near the lateral edges of the central protrusion, so that for the upper part as well, the spacing of the engagement elements can be selected to be relatively great; as a result, both the upper part and the lower part

can be reliably secured against skewing.

It should already be noted here that the words "lower part" and "upper part" do not necessarily say anything about the installed position of the intervertebral implant in the 5 spinal column; the part called the "lower part" could in fact be above in the spinal column. What is essential is merely that the upper part and lower part define the intervertebral implant on opposite sides of the implant.

It is especially advantageous if the upper part and/or 10 the lower part is embodied in substantially platelike fashion; these parts naturally, in accordance with the design of the invention, have protrusions and recesses that are oriented toward the respectively other part. The platelike embodiment, however, leads as a whole to a very low 15 structural height of the intervertebral implant.

In a preferred embodiment, the lower part and the upper part each have a respective receptacle for a pivot insert. This pivot insert, which is placed between the upper part and lower part after the insertion of the intervertebral implant, 20 supports the upper part and lower part against one another; it takes on a resilient function, for instance, and furthermore leads to a certain pivotability of the two parts of an intervertebral implant relative to one another, so that a pivotability of the adjacent vertebra is thus attainable as 25 well.

In particular, it is advantageous if the pivot insert has at least one spherical support face, which engages the correspondingly spherically shaped receptacle.

It is favorable if the spherical receptacle is disposed

in the central protrusion of the upper part.

It is also advantageous if the central indentation of the lower part forms the receptacle for the pivot insert.

According to a preferred embodiment of the invention, 5 it is provided that the pivot insert can be inserted from the side into the receptacle, which has the engagement elements for a manipulation instrument. This is the side from which the upper part and lower part are introduced into the 10 intervertebral space, and it is also from this side that the pivot insert can then be thrust between the already-inserted parts of the intervertebral implant.

It is favorable if the pivot insert is insertable into the receptacle along a guide.

15 In that the insert as well is preferably embodied substantially in platelike fashion.

An especially favorable design is obtained if the insert substantially completely fills up the central receptacle and with its spherical support face protrudes from the receptacle.

20 The ensuing description of preferred embodiments of the invention serves in conjunction with the drawing to provide further explanation. Shown are:

25 Fig. 1: a perspective exploded view of an intervertebral implant with an upper part, a lower part, and a pivot insert that can be inserted between them;

Fig. 2: a perspective exploded view of the upper part

and the lower part of the intervertebral implant, without an inserted pivot insert;

Fig. 3: a view similar to Fig. 2 with the pivot insert inserted into the lower part;

5 Fig. 4: a perspective view of the upper part and the lower part of the intervertebral implant with maximum mutual proximity;

Fig. 5: a front view of the intervertebral implant of Fig. 4;

10 Fig. 6: a perspective view of the intervertebral implant with the pivot insert inserted; and

Fig. 7: a cross-sectional view of the intervertebral implant of Fig. 6.

15 The intervertebral implant 1 shown in the drawing includes three parts, namely a platelike upper part 2, a platelike lower part 3, and a substantially platelike pivot insert 4.

20 The upper part 2 is embodied flat on its top, thus creating a support face 5, on which various kinds of protrusions 6, 7 are disposed which serve the purpose of anchoring the upper part 2 in a vertebra that rests, with its end face toward an intervertebral space, on the support face 5.

25 The upper part 2 is substantially rectangular in cross section; in the exemplary embodiment shown, a longitudinal edge 8 curves outward.

On the two short sides of this rectangle, the thickness of the platelike upper part 2 is less than in the central region, so that along the short sides of the upper part 2, downward-pointing recesses 9 each extending parallel to these edges are formed that are open toward the outside. The central region of the upper part 2 is located between the two recesses 9 and thus has a greater thickness or height and thus forms a downward-pointing protrusion 10 embodied between the two recesses 9. This protrusion is defined by an underside 11, which extends substantially parallel to the support face 5 and in which there is a spherical indentation 12, which forms a bearing plate for the pivot insert 4.

The lower part 3 of the intervertebral implant 1 is also platelike in embodiment and on its underside has a flat support face 13 with protrusions 14 and 15, which correspond to the protrusions 6 and 7 of the support face 5. On the side remote from the support face 13, the thickness of the lower part 3 is less in the central region than in an outer region. This outer region of greater thickness has the form of a U, with two parallel legs 16, 17, which extend parallel to the short edges of the lower part 3, which in cross section is embodied similarly to the upper part 2, and with a crosspiece 18 that connects the two legs 16 and 17 on one end. The region enclosed by the legs 16 and 17 and the crosspiece 18 forms a central indentation 19, whose area is substantially equivalent to the area of the central protrusion 10 of the upper part 2, while the disposition and length of the legs 16 and 17 correspond essentially to the disposition and length of the recesses 9 on the upper part 2. As a result, it is possible to place the upper 2 and lower part 3 on one another in such a way that the central protrusion 10 of the upper 2 dips into the central indentation 19, while the legs 16 and 17 of the lower part 3

dip into the recesses 9 of the upper part 2 (Fig. 4); in this position, the upper part 2 and lower part 3 have maximum proximity to one another and a minimal structural height.

5 The dimensions are selected such that the various recesses are essentially filled completely by the protrusions dipping into them.

10 Blind bores 20 and 21 are machined into the two legs 16 and 17 of the lower part 3, extending parallel to these legs 16, 17 from their free ends; the diameter of these bores is relatively great in proportion to the height of the legs 16, 17, and this diameter is in fact greater than the thickness or height of the lower part 3 in the region of the central indentation 19.

15 Blind bores 22 and 23, which extend parallel to the blind bores 20 and 21 in the lower part 3, are machined into the central protrusion 10 of the upper part 2, in the vicinity of its side edges. These blind bores 22 and 23 again have a relatively great diameter, which corresponds to a substantial portion of the height of the protrusion 10 and is greater than the thickness of the upper part 2 in the region of the recesses 9.

20 When the upper part 2 and lower part 3 rest tightly against one another in the manner described, the blind bores 20 and 21 of the lower part 3 and the blind bores 22 and 23 of the upper part 2 overlap at least partly in the direction of the height of the intervertebral implant 1, as is clearly shown in Figs. 4 and 5.

The blind bores 20, 21, 22 and 23 serve as receptacles for pinlike extensions of a manipulation instrument, not

shown in the drawing, and thus form engagement elements for this manipulation instrument, which in this way separately engages the upper part 2 and the lower part 3. With this manipulation instrument, it is possible to introduce the
5 upper part 2 and the lower part 3 of the intervertebral implant 1 into an intervertebral space; the very low structural height of the intervertebral implant 1 facilitates this introduction, which can be done essentially without major widening of the intervertebral space.

10 After the introduction of the upper part 2 and lower part 3 in this way, the two parts of the intervertebral implant 1 can be spread apart; that is, their spacing is increased, for instance with the aid of the manipulation instrument that is holding the upper 2 and the lower part 3.

15 In this spread-open position of the upper part 2 and lower part 3, it is possible to thrust the pivot insert 4 between the upper part 2 and the lower part 3.

20 This pivot insert is constructed essentially in the shape of a plate, which has a flat underside 24 and a spherically upward-curved top side 25. The outer dimensions of the platelike pivot insert correspond to those of the central indentation 19 in the lower part 3, so that the pivot insert 4 can be thrust into this indentation, filling it up, specifically from the side toward which the blind bores 20,
25 21, 22, 23 open. Guide strips 26 on the side edges of the pivot insert 4 engage corresponding guide grooves 27 in the legs 16, 17, so that an insertion guide for the pivot insert 4 is formed that fixes it in the lower part 3 after its insertion. The inserted pivot insert 4, after insertion,
30 fills up the indentation 19 and protrudes with its spherically curved top side 25 upward past the top side of

the lower part 3; the spherical top side 25 dips in complimentary fashion into the spherically curved indentation 12 on the underside of the protrusion 10, where with the upper part 2 it forms a ball joint, which enables a certain 5 pivotability of the upper part 2 relative to the lower part 3 (Fig. 7).

The pivot insert 4 can have a detent protrusion 28 on its flat underside 24; when the pivot insert 4 is inserted into the lower part 3, this protrusion locks elastically into 10 a detent recess 29 that is located on the bottom of the indentation 19; as a result, the pivot insert 4 is also fixed in the insertion direction in the indentation 19.

The upper part 2 and lower part 3 are preferably made 15 of physiologically safe metal, such as titanium, while the pivot insert 4 preferably comprises a likewise physiologically safe plastic material, such as polyethylene. These support faces 5 and 13 can be embodied in an especially 20 bone-compatible way; for instance, this surface can be roughened by a coating, so that optimal anchoring to the adjacent bone material is obtained.

CLAIMS

1. An intervertebral implant (1), having an upper part (2) that has a support face (5) for a vertebra and a lower part (3) that has a support face (13) for an adjacent vertebra, on each of which parts engagement elements (20, 21, 5 22, 23), which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, characterized in that the upper part (2) and lower part (3) each have protrusions and recesses (10, 19; 16, 17, 9) aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part (2) has been brought close to the lower part (3) they mesh with one another; and that the engagement elements (22, 10 23; 20, 21) on the upper part (2) and on the lower part (3) are each disposed in protrusions (10; 16, 17) of these parts in such a way that the engagement elements (22, 23; 20, 21) 15 of the upper part (2) and lower part (3) are located side by side and at least partly overlap in the direction of the height of the intervertebral implant (1).

2. The implant of claim 1, characterized in that the engagement elements (20, 21, 22, 23) are insertion openings for pinlike retaining elements of a manipulation instrument.

3. The implant of claim 2, characterized in that the insertion openings (20, 21, 22, 23) extend substantially parallel to the support faces (5; 13).

4. The implant of one of the foregoing claims, characterized in that the lower part (3) has a central indentation (19), opposite the lower support face (13), which indentation is surrounded by a U-shaped edge (16, 17, 18).

5. The implant of claim 4, characterized in that the upper part (2) has a central protrusion (10) that fits substantially in complimentary fashion into the indentation (19).

6. The implant of one of claims 4 or 5, characterized in that the engagement elements (20, 21) of the lower part (3) are disposed on the two ends of the U-shaped edge (16, 17, 18).

7. The implant of one of claims 5 or 6, characterized in that the engagement elements (22, 23) of the upper part (2) are disposed on the central protrusion (10) of the upper part (2).

8. The implant of claim 7, characterized in that the engagement elements (22, 23) of the upper part (2) are disposed near the lateral edges of the central protrusion (10).

9. The implant of one of the foregoing claims, characterized in that the upper part (2) and/or the lower part (3) is embodied in substantially platelike fashion.

10. The implant of one of the foregoing claims, characterized in that the lower part (3) and the upper part (2) each have a respective receptacle (19; 12) for a pivot insert (4).

11. The implant of claim 10, characterized in that the pivot insert (4) has at least one spherical support face (25), which engages the correspondingly spherically shaped receptacle (12).

12. The implant of claim 11, characterized in that the spherical receptacle (12) is disposed in the central protrusion (10) of the upper part (2).

13. The implant of one of claims 10-12, characterized in that the central indentation (19) of the lower part (3) forms the receptacle for the pivot insert (4).

14. The implant of claim 13, characterized in that the pivot insert (4) can be inserted from the side into the receptacle (19), which has the engagement elements (20, 21, 22, 23) for a manipulation instrument.

15. The implant of claim 14, characterized in that the pivot insert (4) is insertable into the receptacle (19) along a guide (26, 27).

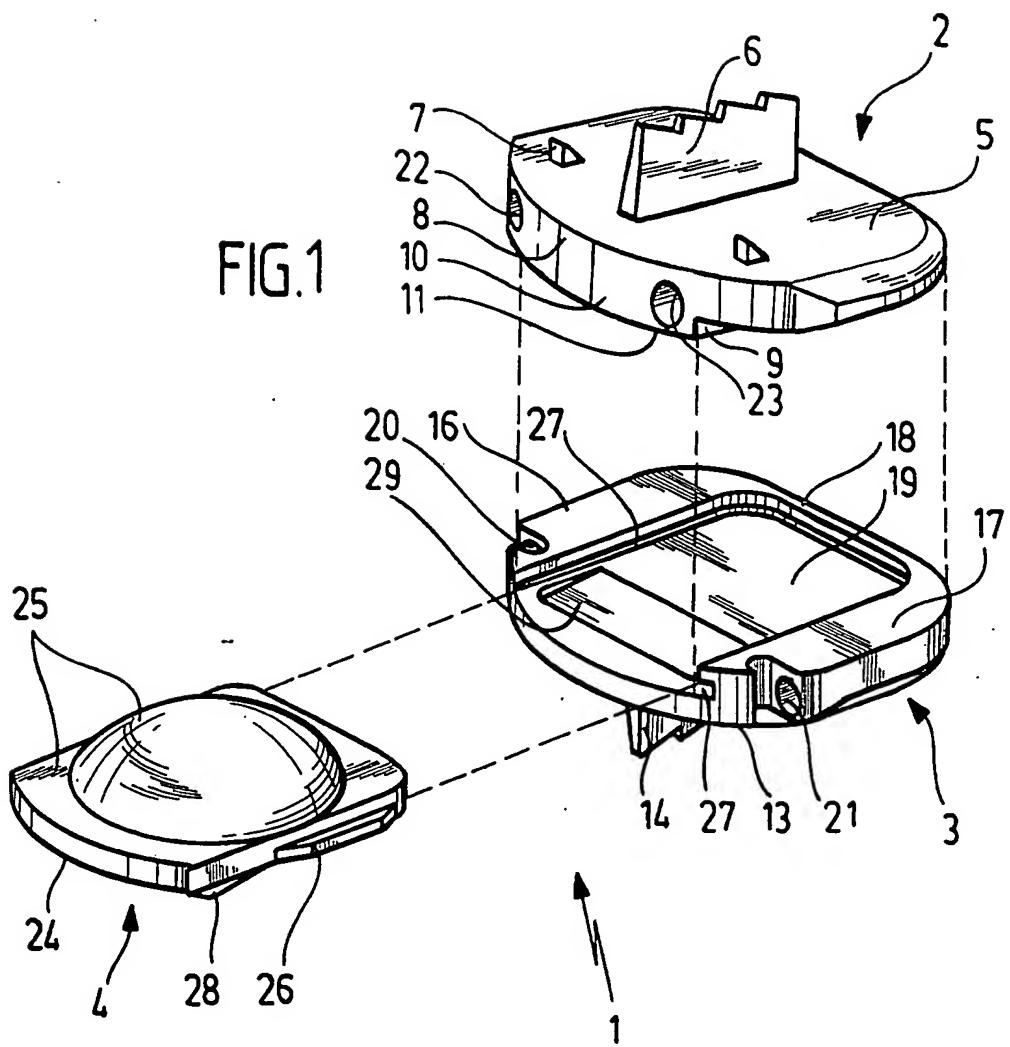
16. The implant of one of claims 10-15, characterized in that the pivot insert (4) is embodied substantially in platelike fashion.

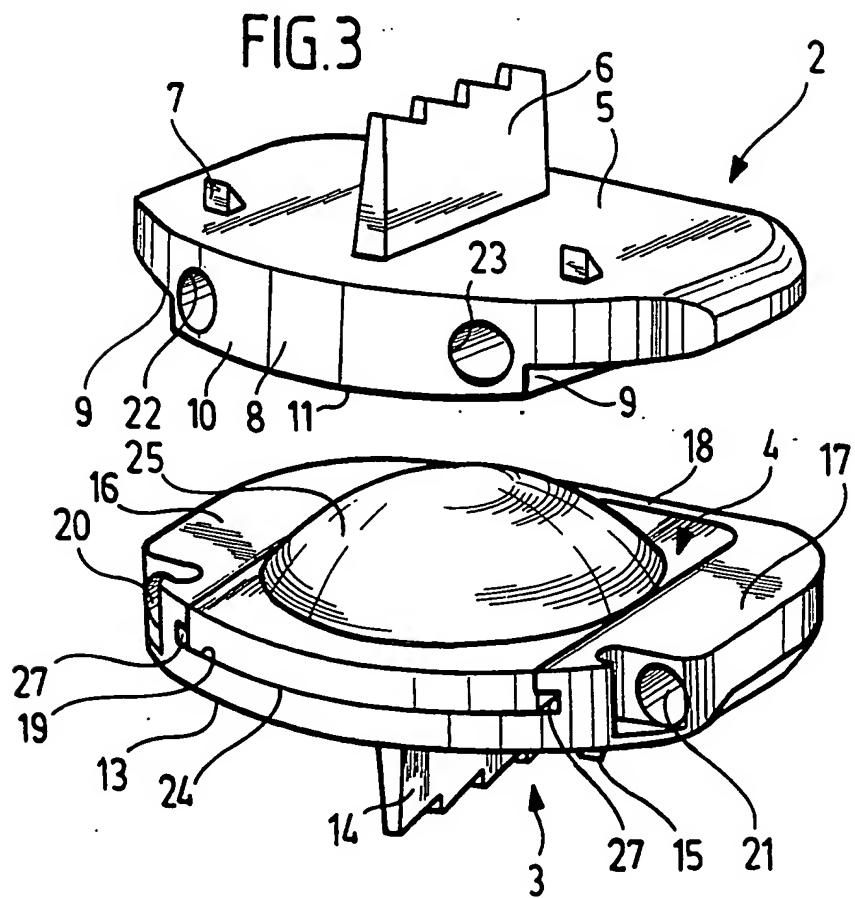
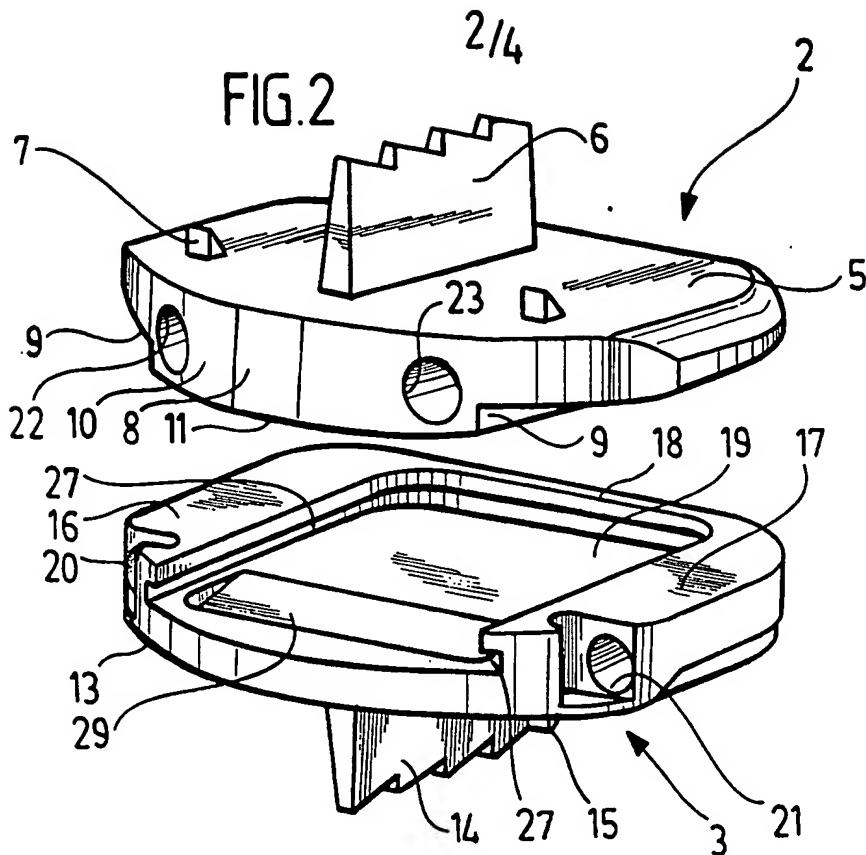
17. The implant of one of claims 11-16, characterized in that the pivot insert (4) substantially completely fills up the central receptacle (19) and with its spherical support face (25) protrudes from the receptacle (19).

ABSTRACT

In an intervertebral implant, having an upper part that has a support face for a vertebra and a lower part that has a support face for an adjacent vertebra, on each of which parts 5 engagement elements, which are accessible from one side of the intervertebral implant, for a manipulation instrument are disposed, in order to minimize the structural height of the intervertebral implant upon insertion into an intervertebral space, it is proposed that the upper part and lower part each 10 have protrusions and recesses aimed at the respectively other part, which are offset laterally from one another in such a way that when the upper part has been brought close to the lower part they mesh with one another; and that the engagement elements on the upper part and on the lower part 15 are each disposed in protrusions of these parts in such a way that the engagement elements of the upper part and lower part are located side by side and at least partly overlap in the direction of the height of the intervertebral implant.

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FIG.4

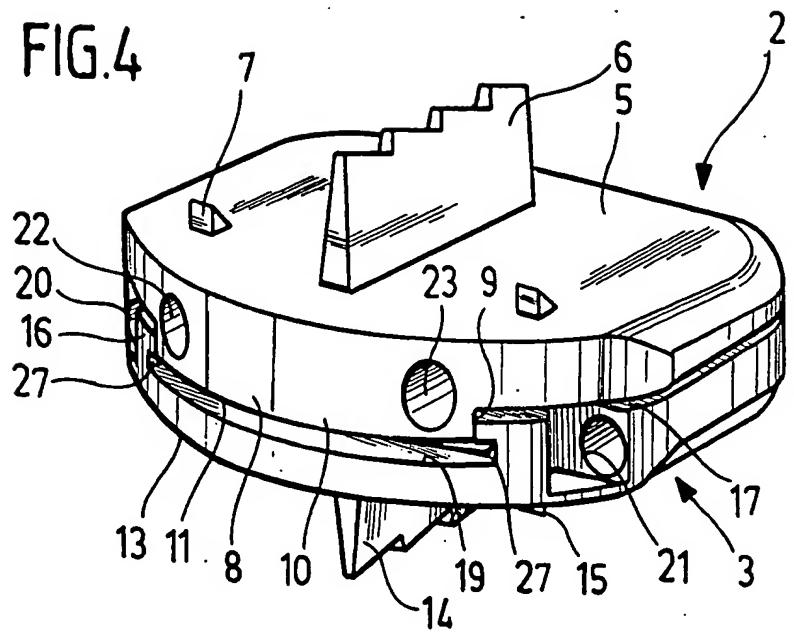
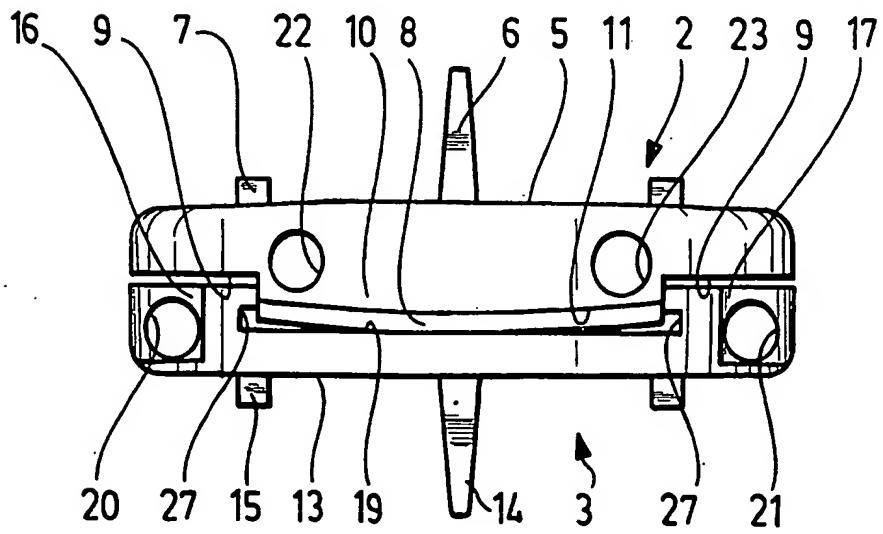


FIG.5



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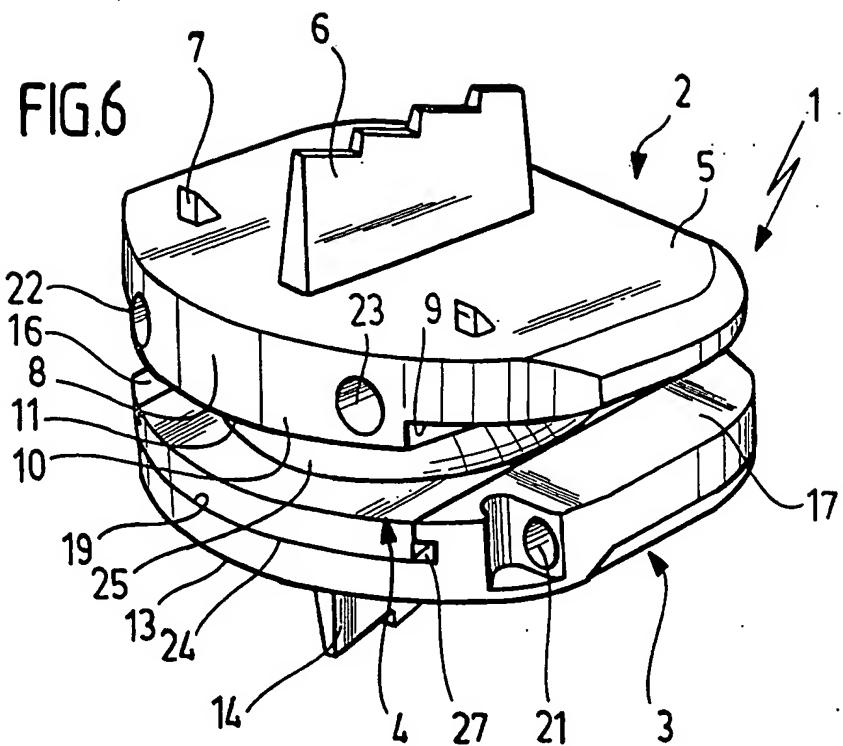
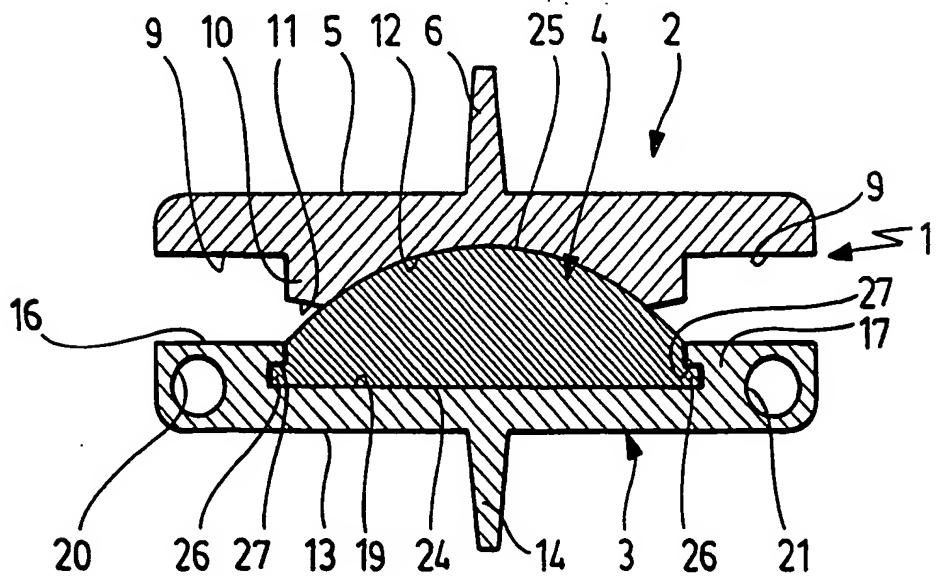
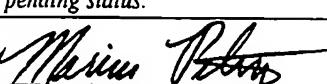


FIG.7



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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. <i>If known, see 37 CFR 1.51</i>
INTERNATIONAL APPLICATION NO. PCT/EP99/04628		INTERNATIONAL FILING DATE 02 JULY 1999	PRIORITY DATE CLAIMED	
TITLE OF INVENTION: INTERVERTEBRAL IMPLANT				
APPLICANT(S) FOR DO/EO/US: MARINAY, Thierry et al.				
Applicant herewith submits to the US Designated/Elected Office (DO/EO/US) the following items and other information:				
<p><input checked="" type="checkbox"/> 1. This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p><input type="checkbox"/> 2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 USC 371.</p> <p><input checked="" type="checkbox"/> 3. This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Art. 22 and 39(1).</p> <p><input type="checkbox"/> 4. A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p><input checked="" type="checkbox"/> 5. A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ul style="list-style-type: none"> <input type="checkbox"/> a. is transmitted herewith (required only if not transmitted by the International Bureau). <input checked="" type="checkbox"/> b. has been transmitted by the International Bureau. <input type="checkbox"/> c. is not required, as the application was filed in the United States Receiving Office (RO/US). </p> <p><input checked="" type="checkbox"/> 6. A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p><input type="checkbox"/> 7. Amendments to the claims of the International Appln. under PCT Article 19 (35 USC 371 (c)(3)) <ul style="list-style-type: none"> <input type="checkbox"/> a. are transmitted herewith (required only if not transmitted by the International Bureau). <input type="checkbox"/> b. have been transmitted by the International Bureau. <input type="checkbox"/> c. have not been made; however, the time limit for making such amendments had NOT expired. <input checked="" type="checkbox"/> d. have not been made and will not be made. </p> <p><input type="checkbox"/> 8. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p><input type="checkbox"/> 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p><input type="checkbox"/> 10. A translation of the annexes to the Int'l Prelim. Exam. Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>				
Items 11. to 20. below concern document(s) or information included:				
<p><input type="checkbox"/> 11. An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.</p> <p><input type="checkbox"/> 12. An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p><input checked="" type="checkbox"/> 13. A First preliminary amendment.</p> <p><input type="checkbox"/> 14. A Second or Subsequent preliminary amendment.</p> <p><input type="checkbox"/> 15. A substitute specification.</p> <p><input type="checkbox"/> 16. A change of power of attorney and/or address letter.</p> <p><input type="checkbox"/> 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 & 35 USC 1.821-825.</p> <p><input type="checkbox"/> 18. A second copy of the published international application under 35 USC 154(d)(4).</p> <p><input type="checkbox"/> 19. A second copy of the English translation of the international application under 35 USC 154(d)(4).</p> <p><input type="checkbox"/> 20. Other items or information: <ul style="list-style-type: none"> <input type="checkbox"/> <input type="checkbox"/> </p> <p><input type="checkbox"/> A copy of the Notification of Missing Requirements under 35 U.S.C. 371.</p> <p><input type="checkbox"/> In the event that a petition for extension of time is required to be submitted herewith, and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 CFR 1.136(a) for an extension of time of as many months as are required to render this submission timely. Any fee is authorized in 17(c).</p>				

Date: 19 December 2001

U.S. APPLICATION NO. (if known) 10/018402	INTERNATIONAL APPLICATION NO. PCT/EP99/04628	ATTORNEY DOCKET NO. P06794US00/MP										
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CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE									
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<input type="checkbox"/> 30 mos. +												
			TOTAL NATIONAL FEE =	\$ 890								
<input type="checkbox"/> Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property			+ \$									
			TOTAL FEES ENCLOSED =	\$ 890								
		<i>Amount to be</i>	<i>Refunded</i>	\$								
			<i>Charged</i>	\$								
<input checked="" type="checkbox"/> a. A check in the amount of \$ 890 to cover the above fees is enclosed. <input type="checkbox"/> b. Please charge my Deposit Account No. 12-0555 in the amount of \$ to cover the above fees. <input checked="" type="checkbox"/> c. The Commissioner is hereby authorized to charge any additional fees required or credit overpayment to Deposit Account No. 12-0555.												
Note: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.												
SEND ALL CORRESPONDENCE TO:		SIGNATURE:  NAME: Marvin Petry REG. NO.: 22752 PHONE NO.: 703-739-4900 Date: 19 December 2001										
MARVIN PETRY At the address (below) of CUSTOMER NO. 00881. LARSON & TAYLOR, PLC 1199 NORTH FAIRFAX ST. SUITE 900 ALEXANDRIA, VA 22314												

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